

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO:
ALL CASES IDENTIFIED IN **EXHIBIT A**
TO UNDERLYING MOTION

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE OR
LIMIT THE OPINIONS AND TESTIMONY OF DR. SALIL KHANDWALA**

Plaintiffs hereby move this Court to exclude all of the expert testimony proffered by Defendant Ethicon Corp. ("Defendant") expert Dr. Salil Khandwala, M.D. ("Dr. Khandwala") or limit as set forth herein as a General Causation Expert in cases involving the Prolift or Prolift+M devices as well as the components Gynemesh PS and Ultrapro mesh. In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Khandwala is a board certified physician in Urogynecology and Female Pelvic Medicine and Reconstructive Surgery, and Plaintiffs do not challenge his qualifications as such. *See* Exhibit B; Rule 26 Expert Report of Dr. Khandwala at 2. However, Dr. Khandwala offers opinions in this case that exceed the bounds of his qualifications and are founded on insufficient facts and unreliable methodology.¹

Dr. Khandwala's experience in the field of Urogynecology does not render all, or even any, of his opinions necessarily admissible; in this case, Dr. Khandwala's opinions

¹ *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.).

are unreliable, contrary to law, and present a serious risk of confusing the issues and misleading the jury in this case.² As this Court noted, “[j]ust because an expert may be ‘qualified . . . by knowledge, skill, experience, training or education’ does not necessarily mean that the opinion that the expert offers is ‘the product of reliable principles and methods’ or that the expert ‘has reliably applied the principles and methods to the facts of this case.’”³ Here, Dr. Khandwala has not utilized sound methodology in reaching his opinions in these cases, and, accordingly, Dr. Khandwala should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

The Court acts as gatekeeper to determine whether an expert’s testimony is reliable and relevant.⁴ This gatekeeping function applies not only to “scientific” testimony, but also to testimony based on “technical” and “other specialized” knowledge.⁵ The proponent of expert opinion bears the burden of establishing its admissibility.⁶ Where the proponent fails to establish all of the prerequisites of admissibility, the exclusion of expert testimony is within the court’s sound discretion.⁷ The admissibility of expert opinion testimony is governed by the Federal Rules of Evidence.⁸ In a federal court sitting in diversity jurisdiction, the admissibility of expert

² See *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (“[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to ‘be both powerful and quite misleading.’”)(citing *Daubert*, 509 U.S. at 596).

³ *Cisson v. C.R. Bard, Inc.*, 948 F.Supp.2d 589, 612 (S.D.W.Va. 2013).

⁴ *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 598 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); Fed. R. Evid. 702.

⁵ *Kumho Tire Co., Ltd.*, 526 U.S. at 141.

⁶ E.g., *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

⁷ *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997)

⁸ *Daubert*, 509 U.S. at 587.

testimony is a question of and controlled by federal law.⁹ In multidistrict litigation, the law of the transferee circuit governs questions of federal law.¹⁰

ARGUMENT

I. Dr. Khandwala's opinions on safety and efficacy should be excluded because they are based on flawed methodology are fundamentally unreliable.

Whether opining on the safety and effectiveness of the Prolift, Prolift+M, Gynemesh PS, or Ultrapro mesh Dr. Khandwala fails to utilize a reliable methodology in forming his opinions.

A. Dr. Khandwala's opinions comparing native tissue repairs to mesh procedures are fundamentally flawed and unreliable.

Dr. Khandwala's opinions are premised upon overtly unreliable information and methodologies. The dangers of allowing Dr. Khandwala to testify are exemplified by his opinions comparing native tissue repairs to mesh hysteropexy procedures. Ex. B at 14-15; Exhibit D¹¹; Exhibit E¹². Here, Dr. Khandwala attempts to compare the results for his study, consisting of 77 patients, to a population of only 4 patients within the larger native tissue study authored by Lin, et al. Dr. Khandwala opines that the failure rate in the Lin study is "75% for stage III or IV prolapse" but omits from his report that this percentage is based upon an objectively unreliable sample size of 4 patients. Such fundamentally flawed comparisons lacking the reliability required for the admissibility of expert

⁹ See, e.g., *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (quoting *Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1054 (4th Cir. 1986)); *Fraley v. Stoddard, D.P.M.*, 73 F. Supp. 2d 642, 646 (S.D. W.Va. 1999).

¹⁰ See, e.g., *In re Temporomandibular Joint Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1155 (8th Cir. 1996) (citation omitted), *aff'd*, 490 U.S. 122 (1989)); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) ("[i]n the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law").

¹¹ Lin, Tzu-Yin; Su TH; Wang YL; et al.: Risk factors for failure of transvaginal sacrospinous uterine suspension in the treatment of uterovaginal prolapse. *J Formos Med Assoc.* 2005;4: 249–253

¹² Khandwala, Salil; Williams C; Reeves W; Dai J; Jayachandran C. Role of vaginal mesh hysteropexy for the management of advanced uterovaginal prolapse. *J Reprod Med.* 2014 Jul-Aug;59(7-8):371-8

testimony under the Federal Rules of Evidence pervade Dr. Khandwala's opinions and testimony.

Setting aside the unreliable sample size, Dr. Khandwala's methodology remains tangibly flawed as Dr. Khandwala fails to control for the different criteria for success used in the Lin study. The authors of the Lin study considered first-degree recurrent prolapse to be a failure, while Dr. Khandwala's comparative study considered anatomical success to be postoperative POP-Q Stage < II. *Compare* Ex. D at table 2 to Ex. B at 15. This is a significant distinction. Had Dr. Khandwala adjusted his "failure" criteria to be consistent with the Lin study, pure anatomic success in Dr. Khandwala's study (based on POP-Q < Stage I) would decrease to 59.7% instead of the 90.9% figure he cites in his report. Conversely, when the outcomes for the four patients in the Lin study are adjusted for Dr. Khandwala's criteria for "success," the recurrence rate for the subjects with stage III or IV prolapse decreases from the 75% cited by Dr. Khandwala to 50%. Similarly, the success rates for all patients with native tissue repairs in the Lin study increases to approximately 90% under the Dr. Khandwala study's criteria. Dr. Khandwala's unsettling trend of making unsupported comparisons and failing to control for different success metrics abounds throughout his report, rendering his overarching methodology unreliable.

B. Dr. Khandwala's opinions on native tissue repairs are based upon unreliable methodology.

Dr. Khandwala forms his opinions on the safety and effectiveness of mesh compared to native tissue repairs by comparing "success rates" in studies examining native tissue repairs to success rates in mesh studies. However, Dr. Khandwala does not control for the different definitions of success in the studies he cites. First, Dr.

Khandwala looks at only the anatomic (often referred to as “objective”) success rates of native tissue repairs compared to mesh procedures, knowing that different studies utilize different metrics for anatomic success. Ex. B at 5.

Q. Okay. Now, in your expert report you obviously cite a number of studies, and those studies, do they use a consistent definition of objective success?

A. No.

Q. No?

A. It’s all over the place.

See Exhibit C; Deposition of Dr. Khandwala, March 25, 2016 at 76:1-6. Not only are the criteria for objective outcomes “all over the place,” but Dr. Khandwala relies exclusively upon objective measurements of success to opine on problems with native tissue repairs. Ex. B at 5. This approach differs markedly from how Dr. Khandwala quantifies success in his own studies, which utilize composite success metrics incorporating subjective criteria in addition to objective measurements, a methodology Dr. Khandwala believes is superior.

Q. Okay. And you would agree that the composite success is more important to you as a physician?

A. Absolutely.

Ex. C at 86:20-87:3.

Despite acknowledging the superiority of utilizing subjective measurements, Dr. Khandwala selectively examines native tissue repair studies utilizing only outdated objective methodologies, even where subjective information is available.¹³ Ex. B at 5.

¹³ In addition to failing to utilize updated information, Dr. Khandwala also relies on outdated data to support a number of other opinions. For example, Dr. Khandwala’s opinions on the number of women in

For example, the authors of the Weber study (which Dr. Khandwala relies upon to support his assertion that native tissue repairs for anterior compartment prolapse result in a 56% recurrence rate) revisited the results of their original study using criteria for success that more closely aligned with the composite criteria Dr. Khandwala claims to prefer. Using the same patient data from the Weber 2001 study, the authors performed a reanalysis using the updated criteria for anatomical and surgical success. The more recent results are striking in contrast to the high failure rate Dr. Khandwala highlights; Eighty-eight percent of the study population (66/75 women) with relevant follow-up data met the new definition of success (no prolapse beyond the hymen, no prolapse symptoms, and no retreatment) and only 11% of subjects experienced anatomic recurrence beyond the hymen. Further, only 5% of subjects experienced symptomatic recurrence, and no subjects required surgery for recurrence or complications at 1 year. See Exhibit F¹⁴. Dr. Khandwala provides no explanation for his selective omission of more recent and relevant information, especially in light of his stated preference for the inclusion of subjective criteria in assessments of success.

C. Dr. Khandwala ignores subjective measures in his safety and efficacy opinions.

Even when making apples to apples comparisons between mesh and native tissue procedures, Dr. Khandwala ignores or downplays subjective metrics of success, focusing upon objective outcomes to bolster his opinions. Ex. B at 8. The methodology used to form these opinions is squarely at odds with how Dr. Khandwala conducts his own

the US who undergo hysterectomy is premised upon data that borders on 30 years old. *See* Ex. B at 6, 19 (relying upon Wilcox et al (data from 1988-1990) and Farquhar CM, et al (data from 1990-1997).

¹⁴Chmielewski, Lauren; Walters MD, Weber AM, et al. Reanalysis of a randomized trial of 3 techniques of anterior colporrhaphy using clinically relevant definitions of success. *Am J Obstet Gynecol* 2011;205:69.e1-8.

studies and his stated preference for the incorporation of subjective, quality of life information. Ex. C at 86:20-87:3. Despite Dr. Khandwala's preference for incorporating subjective measurements to determine success, his opinions as to the safety and effectiveness of mesh are premised almost exclusively on objective, anatomic, outcomes. Ex. B at 10. ("Overall, most trials report better anatomic success rates in the mesh-based procedures especially when it concerns the anterior compartment.").

Not only does Dr. Khandwala focus predominantly on objective measurements, he selectively omits outcomes utilizing subjective criteria throughout his report, even where the cited studies included such information or the information is readily available. For example, Dr. Khandwala cites to two studies (Nguyen and Vollebregt), to compare anatomic cure rates between native tissue and mesh procedures but omits from his comparison any discussion of the subjective outcomes assessed by the two studies. These omissions are not without consequence as the patient questionnaires in the Vollebregt study demonstrated similar functional outcomes between anterior colporrhaphy and mesh procedures. See Exhibit G¹⁵; Exhibit H¹⁶; Ex. B at 10. Because Dr. Khandwala selectively discounts information he otherwise considers important when rendering non-litigation opinions, his opinions are unreliable and must be excluded.

D. Dr. Khandwala's opinions on the safety and effectiveness of the Prolift based on his own research are unreliable.

¹⁵ Nguyen, John N; Burchette RJ. Outcome after anterior vaginal prolapse repair: a randomized controlled trial. *Obstet Gynecol.* 2008;111(4): 891-898

¹⁶ Vollebregt A, Fischer K, Gietelink D, van der Vaart C. Primary surgical repair of anterior vaginal prolapse: a randomised trial comparing anatomical and functional outcome between anterior colporrhaphy and trocar-guided transobturator anterior mesh. *BJOG* 2011;118:1518–1527

Dr. Khandwala premises his opinion on the safety and effectiveness of the Prolift on fundamentally unreliable information and his opinion should be excluded accordingly. Dr. Khandwala's opinions on the Prolift device are based largely on his own four year study, yet this study does not meet the threshold of reliability. Ex. B at 12.

Q. Okay. And what is the basis for that opinion?

A. For safe and effective?

Q. Yes, for the Prolift.

A. It's my extensive clinical trial, I mean I have been doing this – I was doing it for almost like four years and followed that after, and we have enjoyed unbelievable results with the Prolift system....

Ex. C at 131:12-18.

Dr. Khandwala later acknowledged that his study was not published, despite attempts at publication. Ex. C at 132:10-14. That the study was rejected by a peer-reviewed journal is reason enough to question the reliability of the information forming the basis of much of Dr. Khandwala's opinion however, in addition to lacking the safeguards provided by the peer review process, Dr. Khandwala and Ethicon refused to provide the data from the study which forms the basis of Dr. Khandwala's opinions on the safety and effectiveness of the Prolift. Ex. C at 132:20-22; 133:1-6. Accordingly, Dr. Khandwala's opinions on the Prolift, insofar as they rely upon unpublished data that Ethicon refuses to disclose, must be excluded.

II. Dr. Khandwala should be excluded from offering opinions concerning the IFU, or biomaterials issues (including degradation and shrinkage).

Dr. Khandwala offers numerous other opinions that are not included in his expert report and are unsupportable or based on an unreliable methodology. Despite omitting

opinions related to biomaterials, degradation and the adequacy of warnings from his rule 26 expert report, Dr. Khandwala, through counsel, indicated that he intended to offer such opinions at trial. Ex. C at 10:3-9. In addition to the inexplicable omission of these opinions from his rule 26 report, Dr. Khandwala's testimony reveals that he lacks the experience, training, or intellectual foundation to offer such opinions at trial. For each reason, independently, and collectively, such opinions should be excluded.

A. Dr. Khandwala should be excluded from offering opinions concerning the IFU.

Dr. Khandwala's expert report makes no mention of the adequacy of the instructions for use ("IFU") for either the Prolift or Prolift+M. Although he indicated his intent to offer opinions on the IFU at trial, he conceded that he has no experience in drafting instructions for use or warnings:

Q. Have you ever been involved in the preparation of an IFU?

A. No.

Q. Drafting an IFU?

A. No.

Q. Have you ever been hired as a consultant to draft an IFU?

A. No.

Q. Has any medical device company ever retained you to help them draft Instructions For Use?

A. No.

Q. Have you ever been approached by a medical device company for your opinion on warnings?

A. Prior to launch?

Q. Yes, prior to launch?

A. No.

Ex. C at 34:18-35:10. Moreover, Dr. Khandwala testified that he does not even rely on or use IFUs in his practice and that, in his experience, neither do other physicians:

Q. Okay. Does the Prolift IFU indicate how to place the mesh tension free?

A. Okay, so let's see, I think the key, as I mentioned, once we read this, it's ultimately, you know, what we do, and that this – I would really count more on the monograph, and I think most of my colleagues when we used to go to the summit, they would count on the monograph more than the IFU. So let's see, where that would be.

Ex. C at 196:6-16. Previously, this Court ruled that when a physician admits that he is not an expert on the IFU, and relies solely on his review of an IFU in comparison to his clinical experience to form his opinions, he is unqualified to testify about the IFU.¹⁷ Here, Dr. Khandwala's opinions are even further removed from the realm of reliability. Not only does he admit that he is not an expert in this area, he does not even use the IFU in his practice and believes that his colleagues do not either. In the absence of professional experience in using IFUs, and particularly the IFUs for this product, Dr. Khandwala is not qualified to opine on their adequacy, and his opinions must be excluded.

B. Dr. Khandwala's opinions on biomaterials, biocompatibility, and foreign body responses must be excluded.

¹⁷ *Tyree v. Boston Sci. Corp.*, MDL No. 2326, 2014 U.S. Dist. LEXIS 155138, *178-80 (S.D.W.Va. Oct. 29, 2014) (Excluding Dr. Culligan's opinions on the DFU due to lack of expertise, when his opinion was based only on his reading of the DFU compared to his clinical experience, and his prior involvement in drafting a DFU required use of a regulatory expert to determine content.).

Dr. Khandwala has similarly conceded that he is not a biomaterials expert and has no knowledge of the biomaterial properties of polypropylene mesh for pelvic organ prolapse:

Q. Any background in polymer science?

A. Myself? So if I have any training in polymer science, no.

Q. Are you a biomaterials expert?

A. No.

Ex. C at 93:8-12.

In light of these concessions alone, Dr. Khandwala should be excluded from opining on the properties of polypropylene mesh. Additional testimony further supports this conclusion, as Dr. Khandwala admitted he had never conducted any bench testing on any of the products at issue or polypropylene at all, had never conducted an evaluation of explanted mesh, has no expertise in biofilm, pathology, polymer chemistry, or toxicology. Ex. C at 93:13-94:15. Indeed, despite alleging to offer an opinion on biocompatibility, Dr. Khandwala testified at his deposition that he could not even speak to whether the Gynemesh PS and Ultrapro mesh created different foreign body reaction at all. Ex. C at 203:2-6.

To wit, Dr. Khandwala concedes not only that he has never studied the inflammatory response to implanted mesh but that, he does not study effects that he does not already believe exist.¹⁸

Q. Did you ever study the inflammatory response of the body to implanted mesh?

¹⁸ This sort of conclusory circular logic pervades many of Dr. Khandwala's opinions in which he refuses to study what he does not already believe exists. Ex. C 89:6-8; 118:5-8.

A. I don't think that exists. So I would not be studying something I don't believe exists. Ex. C at 96:24-97:3

Because Dr. Khandwala has no expertise in these fields, his opinions concerning biocompatibility and foreign body responses to the mesh, to the extent he is offering an opinion at all, must be excluded.

C. Dr. Khandwala's opinions on degradation and contraction must be excluded.

Dr. Khandwala's opinions on degradation or contraction are unreliable and must be excluded. In previous rulings, this Court has looked to the expert's ability to provide reasoned explanations for his opinions on the physical properties of polypropylene mesh—and has determined that when these opinions are only general in nature, and based only on the gross examination of mesh, there is no reliable scientific methodology for these opinions.¹⁹ Dr. Khandwala opines in one solitary sentence of his report that polypropylene mesh does not contract. Ex. B at 17. In his deposition, Dr. Khandwala explained mesh contraction is not something he believes in at all, highlighting a pervasive facet of Dr. Khandwala's methodology; that where he does not believe in something, he does not study it:

Q. Any publications on the degradation of mesh?

A. No.

Q. Have you ever published on the shrinkage of mesh?

A. I don't understand these terms, though, but no.

¹⁹ *Tyree*, 2014 U.S. Dist. LEXIS 155138 at *171-76 (excluding expert's opinions on the physical properties of mesh, including degradation, when his opinions were based only on his general gross examination of explanted mesh, without ever performing any kind of testing or measurements).

Q. Have you ever published a study on mesh contracting or changing shape once it's implanted?

A. I don't even believe in that.

Ex. C at 89:2-8; 91:2-93:5.

Dr. Khandwala relies upon a very limited and flawed body of evidence to form his opinions on shrinkage. The entirety of the evidence Dr. Khandwala relies upon consists; an ultrasound study. Ex. B at 17. The ultrasound study cited by Dr. Khandwala used AMS mesh rather than the Gynemesh PS or Ultrapro mesh used in either the Prolift or Prolift +M. See Exhibit I.²⁰ Though Dr. Khandwala admitted that he was not sure which mesh was used in the study, he incorrectly believed it was one of the two meshes manufactured by Ethicon. Ex. C at 90:21-91:1. Because Dr. Khandwala lacks any independent expertise in polypropylene or polymer science, his opinion rests upon the unsupported assumption that all polypropylene mesh exhibits the same behavior in vivo. There is no objective support for Dr. Khandwala's opinion that the Prolift and Prolift+M have the same properties as other meshes and Dr. Khandwala's opinion to that end must be precluded by this Court.

Similarly, Dr. Khandwala's opinions based on his own observations fail to meet the threshold of reliability. Dr. Khandwala testified that because he studies the effects of mesh on the vagina that these observations are a proxy for the effects of the vagina on mesh. Ex. C at 90:12-20. Dr. Khandwala's studies and observations do not assess whether mesh shrinks but only whether the vagina has been shortened. These

²⁰ Dietz, Hans Peter; Erdmann M, Shek KL. Mesh contraction: myth or reality? Am J Obstet Gynecol 2011;204:173.e1-4.

observations suffer from the methodological flaw that it is impossible to determine whether vaginal width was impacted by mesh contraction, a necessary measurement to determine whether shrinkage occurred.²¹

Moreover, it is not apparent from Dr. Khandwala's report or testimony that he accounted for the abundant scientific literature supporting the premise that polypropylene mesh contracts or even cares to study the subject:

Q. Prolift+M. Any studies on the shrinkage of mesh that involve the Prolift?

A. I don't believe in shrinkage of mesh.

Ex. C at 90:4-6. This Court has held that such conclusory statements that fail to take into account contrary scientific literature, data, and studies must be excluded.²²

To the extent Dr. Khandwala has any independent basis to support his opinion that mesh does not contract, his opinion suffers from the same fundamental methodological flaws. When asked the basis of his opinion that polypropylene mesh implants do not shrink, Dr. Khandwala testified:

Going further, when I have removed in a few cases those exposed pieces, they were strong as though I had just put in yesterday, so nothing happened to this. Despite the fact that it has been exposed to the vaginal flora, nothing changes. So there is no contraction, nothing happens. So my clinical experience clearly shows that this does not happen and it has been supported in literature also.

Ex. C at 115:19-116:1. However, Dr. Khandwala testified that he had never performed a microscopic evaluation of explanted mesh, never conducted any bench testing in mesh,

²¹ Exhibit J, Elmér, Caroline; Altman D, Engh ME, Axelsen S, Väyrynen T, Falconer C; Nordic Transvaginal Mesh Group. Trocar-guided transvaginal mesh repair of pelvic organ prolapse. *Obstet Gynecol.* 2009 Jan;113(1):117-26

²² *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, *29-35 (S.D.W.Va. Sept. 29, 2014).

and could only point to a single pathology report referencing explanted mesh. Ex. C at 94:2-95:19. Dr. Khandwala acknowledged the difficulty a physician would have in assessing degradation or shrinkage with the naked eye, contradicting his assertion that mesh does not contract because he has not observed it:

The size of the mesh pore size is about 24 millimeters. There's no way any physician goes and starts measuring these pores and sees if it's constant or not. It is impossible for anyone to say whether it's constant or not.

Ex. C at 123:2-6.

Once again, Dr. Khandwala bases his opinions on the very type of “gross examination” that this Court has held to be insufficient under *Daubert*.²³ In the absence of any literature or testing on shrinkage of Gynemesh PS or Ultrapro mesh, Dr. Khandwala has no basis for his opinions and they must be excluded from this case.

Dr. Khandwala's opinions on degradation of mesh suffer from the same flaws as his opinions on shrinkage. Not only has Dr. Khandwala never published on the topic of degradation, his opinions on degradation, like mesh shrinkage, are limited to his less than scientific observations. Ex. C at 89:2-3. Dr. Khandwala's opinion on degradation is premised exclusively on his assumption that because excised pieces of mesh, viewed through the naked eye, looks and feel the same as it did prior to implantation, that no degradation occurs. Ex. C at 115:15-21. As this Court previously noted: “[a]bsence of evidence is not evidence of absence.”²⁴ At best, Dr. Khandwala bases his opinions on the very type of “gross examination” that this Court has held to be insufficient under *Daubert*.²⁵ Absent any foundation, Dr. Khandwala's opinions on mesh degradation must

²³ *Tyree*, 2014 U.S. Dist. LEXIS 155138 at *169-75.

²⁴ *Tyree*, 2014 U.S. Dist. LEXIS 155138 at *183-85.

²⁵ *Tyree*, 2014 U.S. Dist. LEXIS 155138 at *169-75.

be excluded because Dr. Khandwala is wholly unqualified to offer these opinions, and also because they lack any sound basis and are entirely unreliable.

D. Dr. Khandwala is not qualified to testify on the porosity and stiffness of mesh

Dr. Khandwala's opinions on the porosity, stiffness, and the technical qualities of Gynemesh PS and Ultrapro mesh should be excluded as unreliable. Dr. Khandwala's opinions on the porosity and qualities of Ethicon mesh are based upon limited and insufficient data. Ex. B at 11-12. Further, Dr. Khandwala admitted that he has never published on the porosity of mesh and has never personally examined the pore size of any of the Ethicon meshes absent observations with the naked eye. Ex. C at 88:23-89:1; 115:19-116:1. Previously this Court has held that basing an opinion merely on the occasional examination of products "is not a reliable scientific methodology to reach these generalized conclusions."²⁶

Similarly, Dr. Khandwala's opinions on the lateral and longitudinal stiffness of Ultrapro mesh lack reliability. Dr. Khandwala opines that after absorption of poliglecaprone-25 in the Ultrapro mesh, "the lateral stiffness of the mesh is maintained however, the longitudinal stiffness decreases allowing for the expansion of the neighboring viscera and hence potentially decreasing the potential risk of dyspareunia." Ex. B at 12. It is evident from the opinion itself that Dr. Khandwala is only opining on a hypothetical result, however, his testimony confirms that he has no basis for offering this opinion:

Q. So I guess my question is, is there an actual way to measure the objective lateral support of the Prolift+M mesh once it's implanted?

²⁶ *Id.*

A. I don't know.

Ex. C at 124:3-6. Moreover, when asked if his hypothesis was confirmed by his results (whether he had seen decreased dyspareunia rates between his results with the Prolift and Prolift+M) Dr. Khandwala acknowledged that he had seen no such effect:

“I don't think I've noticed the difference, and I can't really compare these to studies per se because they're not head-to-head comparisons.”

And went on to testify that:

“So I can say – so my opinion is that there's essentially no difference clinically between the Prolift and Prolift+M that I experienced

Ex. C at 127:10-13; 129:13-15. Accordingly, because Dr. Khandwala's opinions on the beneficial effects of Ultrapro mesh are pure conjecture and unsupported by his own clinical observations, they must be excluded.

CONCLUSION

For each of the reasons set forth above, the Plaintiffs respectfully request that this Honorable Court preclude Dr. Khandwala from offering any opinions and specifically from offering opinions on the following topics:

1. The safety and efficacy of the Prolift and Prolift+M devices;
2. The safety and efficacy of other polypropylene devices for the treatment of pelvic organ prolapse;
3. His own clinical experience related to the Prolift and Prolift+M;
4. Polypropylene material properties, including shrinkage and contraction;
5. Polypropylene degradation;
6. Biomaterials issues; and
7. The adequacy of the instructions for use accompanying the Prolift and Prolift+M devices.

Dated: April 21, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, a true and correct copy of this document was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Aimee H. Wagstaff, Esq.